

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>WEST PHARMACEUTICAL SERVICES, INC.,</b>	:	
	:	
<b>Plaintiff,</b>	:	
	:	<b>CIVIL ACTION</b>
	:	
<b>v.</b>	:	<b>NO.</b>
	:	
<b>INNOVATIVE DRUG DELIVERY SYSTEMS, INC.,</b>	:	
	:	
<b>Defendant.</b>	:	

**NOTICE OF REMOVAL**

In accordance with 28 U.S.C. §§ 1441 and 1446, defendant Innovative Drug Delivery Systems (“IDDS”), by its undersigned counsel, files this Notice of Removal on the following grounds:

1. On or about August 3, 2005, an action was commenced in the Court of Common Pleas, County of Chester, entitled West Pharmaceutical Services, Inc., v. Innovative Drug Delivery Systems, Inc., Civil Action No. 05-06081 (the “State Court Action”).
2. Pursuant to 28 U.S.C. § 1446(b), this Notice of Removal is timely, since it is being filed within thirty (30) days of receipt of the Summons and Complaint, which was served on August 12, 2005.
3. This action purports to be a civil action for declaratory judgment.
4. The United States District Court for the Eastern District of Pennsylvania has jurisdiction over this case pursuant to 28 U.S.C. § 1332(a)(1) by reason of the diversity of citizenship of the parties.

5. As to this Court's diversity jurisdiction:

a. Upon information and belief, plaintiff West Pharmaceutical Services, Inc. ("West") is a Pennsylvania corporation with its principal place of business located in Lionville, Chester County, Pennsylvania. For purposes of 28 U.S.C. § 1332(c)(1), West is a citizen of Pennsylvania.

b. Defendant IDDS is a Delaware corporation with its principal place of business located in New York, New York. For purposes of 28 U.S.C. § 1332(c)(1), IDDS is a citizen of both Delaware and New York.

c. Because the named defendant is not also a citizen of Pennsylvania, complete diversity exists in this action.

6. The Complaint makes clear that the amount in controversy in this action exceeds the sum of \$75,000, exclusive of interest and costs, as plaintiff seeks a declaratory judgment to resolve a dispute in the amount of \$1,391,993.

7. The Summons and Complaint is the only pleading or other paper served in the State Court Action. A copy of the Summons and Complaint is annexed hereto as Exhibit A. No further proceedings have been conducted in the State Court Action.

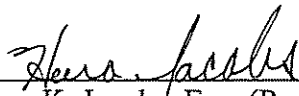
8. A copy of this notice will be filed with the Clerk of the Court of Common Pleas, County of Chester, as required by 28 U.S.C. § 1446(d).

9. Defendant IDDS will give written notice of the filing of this notice to all adverse parties as required by 28 U.S.C. § 1446(d).

WHEREFORE, defendant IDDS respectfully requests removal of this action from the Court of Common Pleas, County of Chester, to the United States District Court for the Eastern District of Pennsylvania.

Dated: September 12, 2005

Respectfully submitted,

By:   
Hara K. Jacobs, Esq. (Pa. ID No. 74832)  
Jason A. Leckerman, Esq. (Pa. ID No. 87915)  
Ballard Spahr Andrews & Ingersoll LLP  
1735 Market Street, 51<sup>st</sup> Floor  
Philadelphia, Pennsylvania 19103  
(215) 864-8209

Attorneys for Defendant Innovative Drug Delivery  
Systems, Inc. ("IDDS")

# EXHIBIT A

Michael L. Kichline  
Attorney I.D. No. 62293  
Joshua G. Schiller  
Attorney I.D. No. 89144  
DECHERT LLP  
4000 Bell Atlantic Tower  
1717 Arch Street  
Philadelphia, PA 19103  
(215) 994-2439

Attorneys for Plaintiff  
West Pharmaceutical Services, Inc.

WEST PHARMACEUTICAL SERVICES,  
INC.,  
101 Gordon Drive  
Lionville, PA 19341

Plaintiff,

v.

INNOVATIVE DRUG DELIVERY  
SYSTEMS, INC.  
787 Seventh Avenue  
New York, New York 10019

Defendant.

COURT OF COMMON PLEAS  
OF CHESTER COUNTY

Civil Action No. 05 - 06081

Declaratory Judgment Complaint

**NOTICE TO DEFEND**

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this Complaint and Notice are served, by entering a written appearance personally or by an attorney and filing in writing with the Court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so, the case may proceed without you and a judgment may be entered against you by the Court without further notice for any money claimed for any other claim or relief requested by the plaintiff. You may lose money or property rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

THE LAWYER REFERENCE SERVICE  
Chester County Bar Association  
15 West Gay Street  
West Chester, PA 19380  
(610) 429-1500

Michael L. Kichline  
Attorney I.D. No. 62293  
Joshua G. Schiller  
Attorney I.D. No. 89144  
DECHERT LLP  
4000 Bell Atlantic Tower  
1717 Arch Street  
Philadelphia, PA 19103  
(215) 994-2439

Attorneys for Plaintiff  
West Pharmaceutical Services, Inc.

WEST PHARMACEUTICAL SERVICES,  
INC.,  
101 Gordon Drive  
Lionville, PA 19341

Plaintiff,

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INNOVATIVE DRUG DELIVERY  
SYSTEMS, INC.  
787 Seventh Avenue  
New York, New York 10019

Defendant.

COURT OF COMMON PLEAS  
OF CHESTER COUNTY

Civil Action No.

Declaratory Judgment Complaint

### COMPLAINT

Plaintiff West Pharmaceutical Services, Inc. ("West") brings this action for declaratory relief in connection with its dealings with Innovative Drug Delivery Systems, Inc. ("IDDS"). West and IDDS were parties to a certain Milestone Agreement until February 8, 2005, at which time, the Milestone Agreement was assigned to a third-party. In connection with the assignment, West and IDDS entered into a certain Side Letter Agreement, dated February 8, 2005. Recently, IDDS delivered a written notice (a) notifying West of purported "deficiencies" in the performance of its obligations and demanding payments allegedly due under the Side Letter

Agreement and (b) notifying West of its intent to hold West liable for unspecified damages allegedly resulting from breaches of the Side Letter Agreement and the Milestone Agreement.

By this action, West seeks, among other relief, declaratory judgments that:

- (i) West has fully satisfied its obligations under the Side Letter Agreement and IDDS is not entitled to any of the payments stipulated in the Side Letter Agreement;
- (ii) the Side Letter Agreement does not allow for recovery of any other alleged damages;
- (iii) the Milestone Agreement (as between West and IDDS) was superseded by the Side Letter Agreement and the Side Letter Agreement now governs the parties' relationship; and
- (iv) West has fulfilled all of its pre-assignment obligations under the Milestone Agreement and IDDS is not entitled to recover any damages or obtain any other relief from West under the Milestone Agreement or any other instrument or theory.

The award of the relief requested herein will resolve an ongoing controversy and will resolve uncertainty regarding the parties' relations. In support of this Complaint, West alleges the following:

#### **THE PARTIES**

1. Plaintiff West Pharmaceutical Services, Inc. ("West" or "WPS") is a Pennsylvania corporation with its principal place of business located in Lionville, Chester County, Pennsylvania.

2. Defendant Innovative Drug Delivery Systems, Inc. ("IDDS") is a Delaware Corporation with its principal place of business located in New York, New York.

### **VENUE**

3. Venue is proper in this Court, pursuant to Pennsylvania Rules of Civil Procedure 1006(b) and 2179(a)(4), because this is a county in which a transaction or occurrence took place out of which the cause of action arose.

### **FACTUAL BACKGROUND**

#### **Agreements Between West and IDDS**

4. On or about August 25, 2000, West and IDDS entered into a License Agreement ("License Agreement") related to the development and licensing of certain pharmaceutical products and delivery systems.

5. On or about September 22, 2000, West and IDDS entered into the Development Milestone and Option Agreement ("Milestone Agreement"). The Milestone Agreement was contemplated in the License Agreement and was related to the development and license of opium alkaloid morphine and/or a salt thereof via the nasal mucosa to humans or animals for the treatment of pain.

6. Both the License Agreement and Milestone Agreement were amended by agreement of West and IDDS on numerous occasions. These amendments include a Letter Agreement, dated September 22, 2000; a Letter Agreement, dated October 9, 2001; an Amendment to License Agreement, dated October 28, 2003; and a First Amendment to Development Milestone and Option Agreement, dated October 28, 2003.



7. On December 24, 2004, West and Archimedes Pharma Limited (“Archimedes”) entered into a Share and Asset Purchase Agreement, whereby West and its wholly-owned subsidiary, West Pharmaceutical Services Group, Ltd. would transfer certain assets to Archimedes. Among the assets to be transferred were those subject to the License Agreement, as amended, and Milestone Agreement, as amended.

8. West sought, and received, IDDS’ consent to the assignment of, *inter alia*, the License Agreement and Milestone Agreement from West to Archimedes. See Assignment Notice, dated February 8, 2005 (attached as Exhibit A). In consideration for IDDS’ consent, West and IDDS agreed, *inter alia*, to amend the License Agreement, see Assignment Notice, dated February 8, 2005, Exhibit B, and enter into the Side Letter Agreement. See Assignment Notice, dated February 8, 2005, Exhibit C. As part of this consent, IDDS “release[d] WPS from further liability [under the Assigned Agreements] to the extent such liability thereunder to the extent such liability arises from events occurring after the Assignment Date . . .”

9. Pursuant to the Side Letter Agreement, West agreed to deliver certain outstanding clinical and manufacturing documentation and data under the assigned Milestone Agreement. The Side Letter Agreement sets forth two schedules of items to be delivered from West to IDDS. Under the terms of the Side Letter Agreement, West was required to deliver all documentation and data in its possession listed on Schedules A and B on or before May 31, 2005. West delivered all of the required documentation and data in its possession to IDDS on or before May 31, 2005.

10. Additionally, the Side Letter Agreement listed specific amounts to be paid to IDDS in the event that West failed to deliver an item listed on either Schedule A or B of the Side

Letter Agreement. The Side Letter Agreement provided that “the total amount of all payments hereunder by WPS shall in no event exceed \$1,391,993.”

11. The Side Letter Agreement provided that it “represents the entire agreement between the parties with respect to the subject matter hereof, and superseded all written or oral prior agreements or understanding with respect thereto. . .” The agreement is governed by the laws of the Commonwealth of Pennsylvania.

**IDDS’ Claimed “Deficiencies”**

12. On May 26, 2005, IDDS contacted West and claimed “deficiencies” in West’s deliveries to IDDS. See Letter, dated May 26, 2005 (attached as Exhibit B). This letter was sent five days before West was required to deliver any items to IDDS and only contained both vague and unproductive claims or incorrect statements. See Letter, dated May 27, 2005 (attached as Exhibit C).

13. On June 28, 2005, counsel for IDDS wrote to West to notify it of purported “deficiencies” in the performance of West’s obligations under the Side Letter Agreement. See Letter, dated June 28, 2005 (attached as Exhibit D). The letter purports to “notify WPS with specificity of certain deficiencies in the performance of its obligations under the Side Letter, to make formal demand of WPS for the payment of certain amounts in accordance with the Side Letter, and to notify WPS that IDDS intends to hold WPS responsible for damages incurred by IDDS as a result of delays in IDDS’ clinical investigations resulting from WPS’ failure to cooperate with IDDS, as required under the Side Letter and Milestone Agreement.”

14. The June 28, 2005 letter purported to outline “deficiencies” in West’s deliveries to IDDS, but the letter only contains vague allegations of “inadequacies” or incorrect allegations

of failure to deliver. To the contrary, West delivered to IDDS all documentation and data within its possession, and all of the documentation and data was complete and sufficient when it left West's possession and complied with all necessary regulatory and scientific standards.

**WEST'S NEED FOR DECLARATORY RELIEF**

15. The claims of IDDS are baseless and were manufactured by IDDS solely for the purpose of concocting a purported claim. By making these assertions – and threatening to pursue remedies that it has no right to pursue – IDDS is seeking to coerce a wholly unwarranted payment.

16. West has real and compelling reasons to put an end to IDDS' baseless and vague allegations and remove the specter of unnecessary, improper and costly future litigation by IDDS against West.

17. IDDS seeks \$1,391,993 from West even though West has fully discharged its duties and IDDS can offer nothing more than conclusory allegations in support of its claims. The conclusory and wholly unjustified nature of IDDS' claims shows that judicial intervention is necessary to end IDDS' improper attempt to coerce West into payment where none is required.

18. Additionally, declaratory judgment is necessary to clarify the rights and obligations under a contract governed by Pennsylvania law. IDDS has implicitly threatened improper future litigation, including litigation over claimed "delays."

**COUNT I**

**DECLARATION OF COMPLIANCE BY WEST**

19. West repeats and realleges the allegations contained in paragraphs 1 – 18 above as if fully set forth herein.

20. West has stated an actual controversy, which is definite, concrete, and right for adjudication by this court.

21. West seeks a declaration that it has fully satisfied its obligations under the Side Letter Agreement and IDDS is not entitled to any of the payments stipulated in the Side Letter Agreement.

22. This requested declaration would resolve and terminate the controversy alleged above conclusively and remove uncertainty created by IDDS' allegations.

WHEREFORE, West respectfully requests that this Honorable Court (i) enter a judgment declaring that West has fully satisfied its obligations under the Side Letter Agreement and IDDS is not entitled to any of the payments stipulated in the Side Letter Agreement; (ii) award West reasonable attorney's fees and costs; and (iii) award such other and further relief as the Court deems proper.

## **COUNT II**

### **DECLARATION OF LIMITATION OF REMEDY UNDER SIDE LETTER AGREEMENT**

23. West repeats and realleges the allegations contained in paragraphs 1 – 22 above as if fully set forth herein.

24. In its demand letter, IDDS claims that "IDDS intends to hold WPS responsible for damages incurred by IDDS as a result of delays in IDDS' clinical investigations resulting from WPS' failure to cooperate with IDDS, as required under the Side Letter . . . ." IDDS' claim for damages is improper under both the Assignment Notice, dated February 8, 2005, and the Side Letter Agreement. Among other things, the Assignment Notice specifically releases West from

such liability and the Side Letter Agreement contains IDDS' sole remedy, namely payment of the specified liquidated amounts.

25. IDDS' claim has created the threat of ongoing litigation by IDDS against West in order to improperly extract payment from West.

26. West seeks a declaration that IDDS' sole remedy (if any) under the Side Letter Agreement is payment of the specified liquidated amounts and that IDDS has no right to any other form of damages under the Side Letter Agreement.

27. This requested declaration would resolve and terminate the controversy alleged above conclusively and remove uncertainty created by IDDS' allegations.

WHEREFORE, West respectfully requests that this Honorable Court (i) enter a judgment declaring that IDDS' sole remedy (if any) under the Side Letter Agreement is payment of the specified liquidated amounts and that IDDS has no right to any other form of damage under the Side Letter Agreement; (ii) award West reasonable attorney's fees and costs; and (iii) award such other and further relief as the Court deems proper.

### **COUNT III**

#### **DECLARATION THAT THE MILESTONE AGREEMENT WAS SUPERSEDED BY THE SIDE LETTER AGREEMENT**

28. West repeats and realleges the allegations contained in paragraphs 1 – 27 above as if fully set forth herein.

29. As alleged above, the IDDS demand letter states that "IDDS intends to hold WPS responsible for damages incurred by IDDS as a result of delays in IDDS' clinical investigations resulting from WPS' failure to cooperate with IDDS, as required under . . . the Milestone Agreement."

30. The Side Letter expressly states that it “supersedes all written or oral prior agreements or understanding” with respect to the subject matter of the Side Letter, namely the License Agreement and Milestone Agreement. As between West and IDDS, The Side Letter Agreement was intended to –and did indeed – supercede the License Agreement and Milestone Agreement as defining all obligations, duties, and rights as between West and IDDS.

31. IDDS’ reference to some unspecified requirement under the Milestone Agreement only serves to create further uncertainty.

32. West seeks a declaration that the Milestone Agreement (as between West and IDDS) was superseded by the Side Letter Agreement and the Side Letter Agreement above governs the parties’ relationship.

33. This requested declaration would resolve and terminate the controversy alleged above conclusively and remove uncertainty created by IDDS’ allegations.

WHEREFORE, West respectfully requests that this Honorable Court (i) enter a judgment declaring that the Milestone Agreement (as between West and IDDS) was superseded by the Side Letter Agreement and the Side Letter Agreement above governs the parties’ relationship; (ii) award West reasonable attorney’s fees and costs; and (iii) award such other and further relief as the Court deems proper.

#### COUNT IV

#### **DECLARATION THAT WEST HAS FULFILLED ITS PRE-ASSIGNMENT OBLIGATIONS AND IDDS HAS NO RIGHT TO RECOVERY**

34. West repeats and realleges the allegations contained in paragraphs 1 – 33 above as if fully set forth herein.

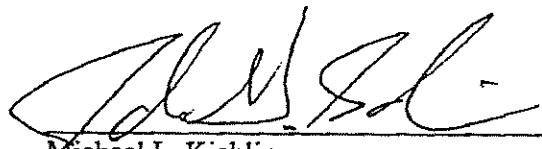
35. As alleged above, the IDDS demand letter stated that “IDDS intends to hold WPS responsible for damages incurred by IDDS as a result of delays in IDDS’ clinical investigations resulting from WPS’ failure to cooperate with IDDS, as required under . . . the Milestone Agreement.”

36. West has fulfilled all of its pre-assignment obligations under the Milestone Agreement.

37. West seeks a declaration that IDDS is not entitled to recover any damages or obtain any other relief whatsoever from West under the Milestone Agreement or any other instrument or theory.

38. This requested declaration would resolve and terminate the controversy alleged above conclusively and remove uncertainty created by IDDS’ allegations.

WHEREFORE, West respectfully requests that this Honorable Court (i) enter a judgment declaring that IDDS is not entitled to recover any damages or obtain any other relief whatsoever from West under the Milestone Agreement or any other instrument or theory; (ii) award West reasonable attorney's fees and costs; and (iii) award such other and further relief as the Court deems proper.



Michael L. Kichline

Attorney I.D. 62293

Joshua G. Schiller

Attorney I.D. 89144

DECHERT LLP

4000 Bell Atlantic Tower

1717 Arch Street

Philadelphia, PA 19103-2793


Attorneys for Plaintiff

West Pharmaceutical Services, Inc.



**VERIFICATION**

I, John R. Gailey III, hereby verify that the statements made in the foregoing Civil Action Complaint are true and correct to the best of my knowledge, information and belief. I understand that false statements herein are made subject to the penalties of 18 Pa. C.S.A. § 4904 relating to unsworn falsification to authorities.

  
A handwritten signature in black ink, appearing to read 'John R. Gailey III', is written over a horizontal line.

Date:

August 3, 2005

# EXHIBIT A

February 8, 2005

Fred H. Mermelstein, Ph.D.  
President and Chief Executive Officer  
Innovative Drug Delivery Systems, Inc.  
130 West 42<sup>nd</sup> Street - 12<sup>th</sup> Floor  
New York, NY 10017

Re: Assignment Notice

Dear Sir or Madam:

West Pharmaceutical Services, Inc. ("WPS") hereby requests that Innovative Drug Delivery Systems, Inc. ("IDDS") consents to the assignment of the agreements set forth on Exhibit "A" hereto (collectively, the "Assigned Agreements") by WPS to Archimedes Pharma Limited ("Archimedes") or any of its subsidiaries (each of Archimedes or any of its subsidiaries, an "Assignee") in connection with a sale of certain of WPS's assets to an Assignee pursuant to the Share and Asset Purchase Agreement between WPS, West Pharmaceutical Services Group, Ltd. and Archimedes which is scheduled to occur on or about February 7, 2005 (the "Assignment Date"). In connection therewith, Assignee has agreed to assume all of WPS's obligations and liabilities under the Assigned Agreements that by their respective terms are required to be paid, performed or discharged after the Assignment Date (the "Assumption").

Archimedes is a company registered in England and Wales under company number 02360391, newly formed to acquire and engage in the drug delivery and research business as currently conducted by WPS. The contact information of Archimedes is as follows:

Archimedes Pharma Limited  
10 Upper Bank Street  
London E14 5JJ  
Attention: Nicholas Lowcock  
Telecopier: [44]207-321-0881

Please indicate your consent, for all purposes under the Assigned Agreements, including without limitation, to the assignment of the Assigned Agreements by WPS to Assignee and to the waiver of compliance with any applicable notice requirements under the Assigned Agreements. Notwithstanding the foregoing, WPS agrees that it will comply

Innovative Drug Delivery Systems, Inc.

February 8, 2005

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with, and remain bound by, the Confidentiality Agreement, dated August 24, 2000, by and among WPS, West Pharmaceutical Services Drug Deliver & Clinical Research Center, Limited (the "Company"), West Pharmaceutical Services Lakewood, Inc., Paramount Capital Investments, LLC and IDDS (the "Confidentiality Agreement") subsequent to the Assignment Date.

In consideration of such consent to assignment of the Assigned Agreements, WPS and IDDS have agreed as follows:

1. WPS shall have paid outstanding amounts owed to IDDS under that certain Clinical Manufacturing Agreement (Nasal Ketamine) dated November 17, 2000 between WPS and IDDS by delivery of a company check in the amount of \$55,105.
2. WPS and IDDS shall have executed and delivered the Amendment Agreement attached hereto as Exhibit "B".
3. WPS and IDDS shall have executed and delivered the side letter attached hereto as Exhibit "C."


Sincerely,

WEST PHARMACEUTICAL SERVICES,  
INC.

By:   
John R. Gayley III, Vice President

In consideration of the foregoing, the undersigned hereby consents to the assignment of the Assigned Agreements by WPS to Assignee and hereby (i) acknowledges receipt of the amount referred to in paragraph no. 1 above, (ii) confirms the satisfaction of paragraph nos. 2 and 3 above and (iii) waives compliance with the notice requirement and releases WPS from further liability thereunder to the extent such liability arises from events occurring after the Assignment Date, provided that the assignment of the Confidentiality Agreement shall not release WPS from any of its obligations thereunder.

Innovative Drug Delivery Systems, Inc.

By:   
Name: President & CEO  
Title: Fred Weinstein

**Exhibit "A"**

- (1) License Agreement, dated August 25, 2000, as amended, among WPS, the Company and IDDS
- (2) Development Milestone and Option Agreement (Nasal Morphine), dated September 22, 2000, as amended, by and among WPS, the Company and IDDS
- (3) Securities Issuance and Registration Rights Agreement, dated as of September 22, 2000, between IDDS and WPS
- (4) Confidentiality Agreement, dated August 24, 2000, by and among WPS, the Company, West Pharmaceutical Services Lakewood, Inc., Paramount Capital Investments, LLC and IDDS
- (5) Fentanyl Termination Agreement dated as of October 28, 2003 among WPS, the Company and IDDS
- (6) Patent License Agreement dated as of October 28, 2003 among WPS, the Company and IDDS

**Exhibit "B"****Amendment Agreement**

THIS IS AN AMENDMENT AGREEMENT (the "Amendment Agreement"), dated as of February 8, 2005 among West Pharmaceutical Services, Inc., a Pennsylvania corporation, ("WPS") its wholly owned subsidiary West Pharmaceutical Services Drug Delivery & Clinical Research Centre Ltd., a corporation organized under the laws of England and Wales, (together with WPS, the "West Group") and Innovative Drug Delivery Systems, Inc., a Delaware corporation ("IDDS").

**Background**

The West Group and IDDS are parties to a License Agreement, dated as of August 25, 2000, as amended (the "Umbrella License Agreement").

In connection with the assignment of the Umbrella License Agreement in connection with the sale of the West Group's drug delivery business, the parties have agreed to further amend the Umbrella License Agreement.

In consideration of IDDS's consent to the assignment, and intending to be legally bound hereby, the parties agree as follows:

1. Section 6.2.2 of the Umbrella License Agreement is hereby amended to read in its entirety as follows:

"a summary balance sheet for the previous year; provided, however, that this Section 6.2.2 shall be deemed to be satisfied so long as the information to be furnished is readily available to West or any successor or assign (including Archimedes Pharma Limited) on the U.S. Securities and Exchange Commission's internet homepage or at the internet homepage of IDDS or its parent within the applicable time period required under this Section 6.2."

2. Except as expressly set forth above, the Umbrella License Agreement shall continue in full force and effect without further amendment.
3. This Amendment Agreement sets forth the entire agreement between the parties with respect to the subject matter hereof, and supersedes all written or oral prior agreements or understanding with respect thereto. This Amendment Agreement may be executed in counterparts and shall be governed by the laws of the Commonwealth of Pennsylvania without regard to the conflicts of laws principles thereof.

(Signatures on following page)



IN WITNESS WHEREOF, the parties hereto have caused this instrument to be executed in duplicate by their respective duly authorized officers.

INNOVATIVE DRUG DELIVERY SYSTEMS, INC.

By: 

Name: FRED MEARNS, JR.

Title: President & CEO

WEST PHARMACEUTICAL SERVICES, INC.

By: 

Name: John R. Galley III

Title: Vice President

WEST PHARMACEUTICAL SERVICES DRUG DELIVERY & CLINICAL  
RESEARCH CENTRE LTD.

By: 

Name: Donald E. Morel, Jr.

Title: Director

FEB-08-2005 16:14

WEST PHARMACEUTICALSVCS.

610 594 3013 P.07/16

Exhibit "C"

Side Letter

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INNOVATIVE DRUG DELIVERY SYSTEMS, INC.  
130 WEST 42<sup>ND</sup> STREET - 12<sup>TH</sup> FLOOR  
NEW YORK, NY 10036

February 8, 2005

West Pharmaceutical Services, Inc.  
101 Gordon Drive  
Lionville, PA 19342  
Attn: John R. Gailey III, Vice President

Dear Sir or Madam:

In consideration of the consent by Innovative Drug Delivery Systems, Inc. ("IDDS") to the assignment of certain agreements entered into between IDDS and West Pharmaceutical Services, Inc. ("WPS") to Archimedes Pharma Limited ("Assignee") as set forth in the Assignment Notice (the "Assignment Notice"), dated February 7, 2005 between IDDS and WPS, WPS and IDDS have agreed to enter into this side letter agreement ("Side Letter") regarding certain outstanding clinical and manufacturing documentation due from WPS to IDDS under the Development Milestone and Option Agreement among West Pharmaceutical Services Drug Delivery & Clinical Research Centre Ltd., WPS and IDDS dated September 22, 2000 (as amended by the parties through the date hereof, the "Milestone Agreement"). All capitalized terms used herein and not defined herein shall have the meanings given to such terms in the Assignment Notice.

Based upon our mutual discussions, we have reached the agreement set forth below:

1. Schedule A sets forth (i) the outstanding clinical and manufacturing documentation which WPS has indicated it will be unable to deliver prior to Assignment Date and (ii) the corresponding amounts to be reimbursed to IDDS under the Milestone Agreement as a result of the failure of WPS to provide such outstanding documentation.



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WEST PHARMACEUTICALSUCS.

610 594 3013 P.08/16

West Pharmaceutical Services, Inc.  
February 8, 2005  
Page 2

On or before May 31, 2005, WPS shall either (a) provide such missing documentation to IDDS or (b) reimburse IDDS for the missing documents listed on Schedule A, the amount to be determined by reference to Schedule A depending on which items are missing; provided, that the total amount of such payments shall in no event exceed \$391,993.

2. Schedule B sets forth the outstanding clinical and manufacturing documentation which WPS has indicated it will deliver, although for any specific items set forth on Exhibit B, WPS shall only be required to deliver such items as were produced in connection with the clinical trials and in all such cases in which the items were not so produced, WPS shall deliver a reasonable substitute therefor. If WPS does not deliver the outstanding documentation listed on Schedule B by May 31, 2005, WPS will pay, subject to the total monetary limit in Section 3, the following amounts:

a. In the event that WPS does not deliver the documentation set forth in Items (1), (2) and/or (3), WPS shall pay IDDS \$1,000,000;

b. In the event that WPS does not deliver the documentation set forth in Item (4), WPS shall pay IDDS \$250,000, and shall reimburse IDDS for costs reasonably incurred in reproducing or recreating such documentation;

c. In the event that WPS does not deliver the documentation set forth in Item (5), WPS shall pay IDDS \$250,000, and shall reimburse IDDS for costs reasonably incurred in reproducing or recreating such documentation; and

d. In the event that WPS does not deliver the documentation set forth in Item (6), WPS shall pay IDDS \$250,000, and shall reimburse IDDS for costs reasonably incurred in reproducing or recreating such documentation.

In addition, if WPS delivers the documentation set forth in Item (1) of Schedule B, and during the term of the Milestone Agreement, the FDA or any Regulatory Agency fails to approve IDDS's NDA for marketing the Licensed Product (as that term is defined in the Milestone Agreement) in the United States or any Member State in the European Union, where such failure to approve is based solely on a deficiency in the underlying formulation development work referred to therein, WPS shall reimburse IDDS for the cost of recreating the development work in question. As used in this paragraph, the terms FDA, Regulatory Agency and NDA shall have the meanings ascribed to those terms in the Milestone Agreement.

3. Notwithstanding anything in this Side Letter, the total amount of all payments hereunder by WPS shall in no event exceed \$1,391,993. In order to qualify for reimbursement under Section 1 or 2 of this Side Letter, IDDS must notify WPS of any deficiencies by June 30, 2005, and failure to provide such notice within that time period shall constitute acceptance by IDDS. Payment by WPS to IDDS for failing to deliver any items under Sections 1 and 2 of this Side Letter shall be made no later July 31, 2005 by

FEB-08-2005 16:15

WEST PHARMACEUTICALSUCS.

610 594 3013 P.09/16

West Pharmaceutical Services, Inc.  
February 8, 2005  
Page 3

company check or wire transfer and shall be deemed to be in full satisfaction of any obligation by WPS in respect of the delivery of documentation under the Milestone Agreement.

4. IDDS shall cooperate with WPS in reviewing promptly all outstanding documentation. IDDS shall also take all necessary action, including providing a letter of authorization, to allow WPS to arrange for the compilation and delivery of electronic SAS datasets from PharmData, Inc. with respect to phase I trial no. GFI 93170, listed as Item (3) on Schedule A. If IDDS fails to take such action, West shall be relieved of any further obligation with respect to that Item.

5. WPS confirms that, as of the date hereof, IDDS has performed all of its obligations required to be performed under the Assigned Agreements and the Assigned Agreements remain in full force and effect.

6. All notices and other communications hereunder shall be in writing and shall be deemed given (a) on the date of delivery if delivered personally; (b) on the date of transmission if sent via facsimile transmission to the facsimile number given below; (c) on the date after delivery to a reputable nationally recognized overnight courier service or (d) three (3) days after being mailed by registered or certified mail (return receipt requested) to the parties at the following addresses (or at such other address for a party as shall be specified by like notice):

(i) If to IDDS, to:

Innovative Drug Delivery Systems, Inc.  
130 West 42<sup>nd</sup> Street - 12<sup>th</sup> Floor  
New York, NY 10036  
Attention: President  
Telecopier: 212 554-4554

(ii) If to WPS, to:

West Pharmaceutical Services, Inc.  
101 Gordon Drive  
Lionville, PA 19341  
Attention: President  
Telecopier: 610 594-3013

With a required copy to:

West Pharmaceutical Services, Inc.  
101 Gordon Drive  
Lionville, PA 19341  
Attention: General Counsel

FEB-08-2005 16:15

WEST PHARMACEUTICALSUCS.

610 594 3013 P.10/16

West Pharmaceutical Services, Inc.  
February 8, 2005  
Page 4

Telecopier: 610 594-3013

7. This Side Letter:

a. represents the entire agreement between the parties with respect to the subject matter hereof, and supersedes all written or oral prior agreements or understanding with respect thereto and may not be amended without the consent of the parties hereto as Assignee is an express third party beneficiary hereof;

b. shall be governed by the laws of the Commonwealth of Pennsylvania without regard to the conflicts of laws principles thereof; and

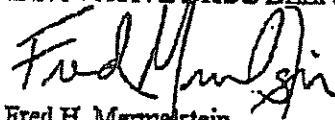
c. may be executed in counterparts, each of which shall be deemed to be an original, but together will constitute one and the same instrument

\* \* \* \* \*

If the foregoing accurately sets forth our mutual agreement with respect to the matters herein, please execute and return the duplicate copy of this letter; you may retain the original for your files.

Very truly yours,

INNOVATIVE DRUG DELIVERY SYSTEMS, INC.



Fred H. Mermelstein  
President and Chief Executive Officer

AGREED TO THIS 8<sup>TH</sup> DAY  
OF FEBRUARY, 2005

WEST PHARMACEUTICAL SERVICES, INC.

By: 

Name: DONALD E. MARR, JR.

Title: PRESIDENT

FEB-08-2005 16:16

WEST PHARMACEUTICALSUCS.

618 594 3813 P.11/16

Schedule A  
Outstanding Documentation, Data & Reports Owed to IDDS

**(1) Pilot Plant and Batch Records**

- List of reconciliation and distribution record for each batch of nasal morphine produced in Europe and the US used in non-clinical and phase I clinical studies.
- Current documentation is inadequate and does not comply with the Code of Federal Regulations Title 21, Sec. 211.196.

**(2) Stability**

- Rationale for each specification and change in specification
  - Specifications used to release clinical drug supply (related impurities >0.1%) in phase I clinical studies does not meet FDA Nasal Spray guideline section III F, and ICH guidelines. Need to address why these guideline were not followed.

**(3) GFI 93170: Phase I, Double-Blind, Single- and Multiple-Dose Study to Assess the Safety, Tolerability, and Pharmacokinetic Profile of Three Ascending Dose Levels of Intranasal Morphine Solution (WPS-004-001) in Healthy Subjects.**

- Electronic SAS datasets not available, therefore IDDS must recreate the database from source documents
- Estimated cost to repeat work is \$45,119

**(4) PPL-629: An Open Label, multi-dose study in healthy male subjects to investigate the deposition, clearance and tolerability of .05% chitosan solution administered in each nostril.**

- Database not available, therefore IDDS must recreate the database from source documents
- Estimated cost to repeat work is \$45,119

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FEB-08-2005 16:16

WEST PHARMACEUTICALSUCS.

610 594 3013 P.12/16

Schedule A  
Outstanding Documentation, Data & Reports Owed to IDDS

(5) DBS/CP28/98: An open label, single center study to assess the tolerability and efficacy of nasal morphine, at doses of 5-80mg, for the relief of breakthrough pain due to cancer in a group of 14 patients.

- o CRFs not available, therefore IDDS must create CRFs from source documents, patient log books, medical records, etc.
- o Database not available, therefore IDDS must recreate the database from source documents
- o Estimated cost to repeat monitoring, data collection and recreate database \$166,636
- o If source data is unavailable or does not meet ICH/GCP guidelines then the estimated cost to repeat the entire study is \$256,636

(6) WSP-99-020: A parallel group, double blind, placebo controlled phase 1 trial to assess the tolerability of intranasal administration of a new excipient, chitosan glutamate.

- o Database not available, therefore IDDS must recreate the database from source documents
- o Estimated cost to repeat work is \$45,119

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FEB-08-2005 16:16

WEST PHARMACEUTICALSUCS.

610 594 3013 P.13/16

**Schedule B**  
**Existing Documentation, Data & Reports Owed to IDDS**

**(1) Delivery to IDDS of a Formulation Development Report signed of by the appropriate West employees**

This report will outline the research and formulation development of Nasal Morphine from inception to the final formulation as reflected in the IND and used in West sponsored phase 1 clinical trials. This report shall contain the following:

- Outline of the rationale for optimum concentration of chitosan at 5mg/ml
  - Supportive documents on each batch tested at various concentrations leading up to 5 mg/mL
  - Data and laboratory results on chemical and physical testing of each batch
  - Documentation outlining the test methods used
- Outline of the rationale for choice of morphine mesylate salt
  - Supportive documents on each alternative salt tested
  - Data and laboratory results on chemical and physical testing of each batch
  - Documentation outlining the test methods used
- Outline of the rationale for pH of 4.0
  - Supportive documents on each batch tested at various pH
  - Data and laboratory results on chemical and physical testing of each batch
  - Documentation outlining the test methods used
- Outline of the rationale for decision to not include an antioxidant
- Outline of the rationale for choice of benzalkonium chloride as the antimicrobial
  - Supportive documents on each batch tested at various concentrations of benzalkonium chloride leading up to 0.15 mg/ml
  - Data and laboratory results on chemical and physical testing of each batch
  - Documentation outlining the test methods used

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WEST PHARMACEUTICALSUCS.

610 594 3013 P.14/16

Schedule B  
Existing Documentation, Data & Reports Owed to IDDS

- Outline of the rationale for use of 1mg of edetate sodium
  - Supportive documents on each batch tested at various concentrations of edetate sodium leading up to 1.0 mg
  - Data and laboratory results on chemical and physical testing of each batch
  - Documentation outlining the test methods used

The report will reference applicable underlying laboratory data (including laboratory notebook entries) and internal and external reports and publications, copies of which shall be attached.

(2) MEO528: A study to assess the tolerability and pharmacokinetic profile of a novel nasal morphine solution when administered to healthy volunteers.

- Investigator Brochure for study

(3) GFI 93170: Phase I, Double-Blind, Single- and Multiple-Dose Study to Assess the Safety, Tolerability, and Pharmacokinetic Profile of Three Ascending Dose Levels of Intranasal Morphine Solution (WPS-004-001) in Healthy Subjects.

- Patient completed CRFs
- IRB Approval to conduct study

(4) PPL-629: An Open Label, multi-dose study in healthy male subjects to investigate the deposition, clearance and tolerability of .05% chitosan solution administered in each nostril.

- Original Protocol (not amendment)
- Investigator Brochure for study
- Patient completed CRFs
- EC Approval to conduct study

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FEB-08-2005 16:17

WEST PHARMACEUTICALSUCS.

610 594 3013 P.15/16

**Schedule B**

**Existing Documentation, Data & Reports Owed to IDDS**

**(5) DBS/CP28/98: An open label, single center study to assess the tolerability and efficacy of nasal morphine, at doses of 5-80mg, for the relief of breakthrough pain due to cancer in a group of 14 patients.**

- Protocol
- Patient Information Sheet
- CVs/licenses for PI
- EC Approval to conduct study
- CRF templates

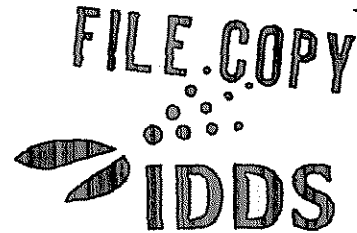
**(6) WSP-99-020: A parallel group, double blind, placebo controlled phase 1 trial to assess the tolerability of intranasal administration of a new excipient, chitosan glutamate.**

- Patient completed CRFs

**COPY CONFIDENTIAL**



# EXHIBIT B



May 26th, 2005

Via Overnight Courier

West Pharmaceutical Services, Inc.  
101 Gordon Drive  
Lionville, PA 19341  
Attn: President

Re: February 8, 2005 Side Letter

Dear Sirs:

We refer to that certain side letter agreement (the "Side Letter") between Innovative Drug Delivery Systems, Inc. ("IDDS") and West Pharmaceutical Services, Inc. ("WPS") dated February 8, 2005 (capitalized terms used in this letter but not otherwise defined shall have the meaning ascribed to such terms in the Side Letter).

The purpose of this letter is to notify WPS of certain deficiencies in the performance of its obligations under the Side Letter and to make a formal demand of WPS to provide the complete documentation required under the Side Letter on or before May 31, 2005, failing which IDDS will demand payment of the amounts to which it is entitled under the Side Letter.

Specifically, under paragraph 1 of the Side Letter, WPS has not yet complied with its obligation to deliver the following documentation specified in Schedule A to the Side Letter:

Description of Documents	Schedule A Item No.	Deficiency
Pilot Plant and Batch Records	1	Materials sent were incomplete and otherwise wholly inadequate
Stability	2	[Materials sent were incomplete and otherwise wholly inadequate]
PPL-629	4	Database not provided
DBS/CP28/98	5	No documentation provided
WSP-99-020	6	Database not provided

Under paragraph 2 of the Side Letter, WPS has not yet complied with its obligation to deliver the following documentation (or reasonable substitutes therefor) specified in Schedule B to the Side Letter:

Innovative Drug  
Delivery Systems, Inc.

130 West 42nd Street, 12th floor  
New York, NY 10036, U.S.A.

☎ (212) 554-4550  
☎ (212) 554-4554  
[www.idds.com](http://www.idds.com)

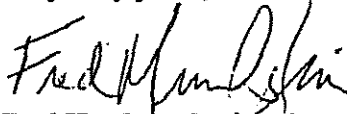
Description of Documents	Schedule B Item No.	Deficiency
Formulation Development Report	1	No report or other documentation provided
PPL-629	4	No documentation provided

In light of the above, IDDS hereby demands that WPS immediately, but in any event not later than May 31, 2005, cure the deficiencies described above, failing which IDDS shall hold WPS responsible for payment of the amounts to which it is entitled under the Side Letter.

Finally, I would like to register my personal disappointment with the manner in which WPS has handled this matter. My staff informs me that there was, at best, nominal cooperation and effort on the part of WPS. In particular, with respect to the database for study number WPS-99-020 conducted by Hammersmith Medicines Research,, we were told by WPS that no database existed, but were subsequently advised by the CRO that the database did in fact exist, and was in fact delivered to WPS on May 3, 2005. This study and database is required for MAA submission and should be delivered to IDDS as soon as possible.

If you have any questions regarding the above, please do not hesitate to contact me at your convenience.

Very truly yours,



Fred H. Mermelstein, Ph.D.  
Chief Executive Officer

cc: West Pharmaceutical Services, Inc.  
101 Gordon Drive  
Lionville, PA 19341  
Attn: General Counsel

[Mr. Douglas Hamilton]

bcc w/o enc.: Jeffrey C. Johnson



# EXHIBIT C



GLOBAL HEADQUARTERS  
101 Gordon Drive • Lionville, PA 19341  
TEL 610-594-2900 • FAX 610-594-3000  
www.westpharma.com

May 27, 2005

*Via Telecopy*

Innovative Drug Delivery Systems, Inc.  
130 West 42<sup>nd</sup> Street – 12<sup>th</sup> Floor  
New York, NY 10036  
Attention: President

Gentlemen:

We were puzzled by your May 26, 2005 letter, which contain allegations that West Pharmaceutical Services, Inc. failed to comply with its obligations under the side letter, dated February 8, 2005, between West and Innovative Drug Delivery Systems, Inc. At a minimum, we did not understand your sending West a notice of purported non-compliance on May 26, when the deadline for West to meet its delivery obligations under the side letter is May 31, 2005.

In fact, the balance of the required items were sent by UPS overnight service on May 26, 2005 and, according to the UPS tracking records, were delivered to your offices 12:32 PM on May 27, 2005, four days before the deadline. For your information, this latest package contains the database for study number WPS-99-020. In addition, the PPL-629 information (Schedule B, Item No. 4) was included in West's initial shipment, sent April 21, 2005. We suggest that IDDS review the information carefully and thoroughly before making further allegations of non-compliance.

West cannot comment on your assertion that the materials sent were "incomplete and otherwise wholly inadequate" except to disagree with that characterization.

West will be more than happy to consider specific requests for additional information if IDDS is willing to be more specific about additional information to which it believes it's entitled, but cannot respond to vague complaints, which West itself considers to be "wholly inadequate."

Very truly yours,

West Pharmaceutical Services, Inc.

By:   
Nicholas Klutznick, Vice President,  
Business Development

cc: John R. Gailey III, Esq.

Global Partners with  
Daikyo Seiko Ltd.  
The West Company Mexico S.A. de C.V.

# EXHIBIT D

**PRYOR CASHMAN SHERMAN & FLYNN LLP**

NEW YORK ALBANY LOS ANGELES

410 PARK AVENUE, NEW YORK, NY 10022-4441 TEL: 212-421-4100 FAX: 212-325-0806

www.pryorcashman.com

JEFFREY C. JOHNSON

DIRECT TEL: 212-325-0118

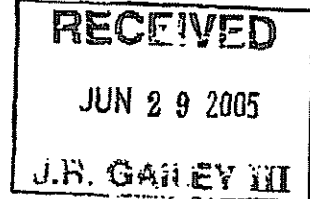
DIRECT FAX: 212-758-0314

johnson@pryorcashman.com

June 28, 2005

**Via Federal Express and Facsimile**

West Pharmaceutical Services, Inc.  
 101 Gordon Drive  
 Lionville, PA 19341  
 Attention: President

**RE: Demand for Payment of \$1,391,993 under February 8, 2005 Side Letter**

Dear Sirs:

This office represents Innovative Drug Delivery Systems, Inc. ("IDDS"). We refer to that certain side letter agreement (the "Side Letter") between IDDS and West Pharmaceutical Services, Inc. ("WPS") dated February 8, 2005 (capitalized terms used in this letter but not otherwise defined have the meaning ascribed to such terms in the Side Letter), as well as IDDS' letter to WPS dated May 26, 2005 and WPS' reply dated May 27, 2005.

The purpose of this letter is to notify WPS with specificity of certain deficiencies in the performance of its obligations under the Side Letter, to make formal demand of WPS for the payment of certain amounts in accordance with the Side Letter, and to notify WPS that IDDS intends to hold WPS responsible for damages incurred by IDDS as a result of delays in IDDS' clinical investigations resulting from WPS' failure to cooperate with IDDS, as required under the Side Letter and the Milestone Agreement.

Specifically, under paragraph 1 of the Side Letter, WPS has failed to provide the following documentation specified in Schedule A to the Side Letter and, accordingly, IDDS is entitled to reimbursement of the following corresponding amounts:

Description	Schedule A Item No.	Deficiency	Reimbursement Amount
Pilot Plant and Batch Records	1	Documentation provided does not comply with DFR Title 21, Sec. 211.196	Unspecified
Stability	2	Specifications do not meet FDA Nasal Spray guideline section III F or ICH guidelines	Unspecified

West Pharmaceutical Services, Inc.  
Attention: President  
June 28, 2005  
Page 2

PPL-629	4	Database not provided	Forty-five thousand one hundred nineteen dollars (\$45,119)
DBS/CP28/98	5	The disc provided by WPS, that purportedly contained the database, contained corrupted data that could not be used	Four hundred twenty-three thousand two hundred seventy-two dollars (\$423,272)

Under paragraph 2 of the Side Letter, WPS has failed to provide the following documentation (or reasonable substitutes therefor) specified in Schedule B to the Side Letter and, accordingly, IDDS is entitled to payments from WPS of the following corresponding amounts:

Description	Schedule B Item No.	Deficiency	Reimbursement Amount
Formulation Development Report	1	The various rationales contained in the report are inadequate for use in connection with a Phase II clinical trial	One million dollars (\$1,000,000)
PPL-629	4	The materials sent were incomplete, and did not include the necessary investigator brochure, consent form or IRB protocol approval.	Two hundred fifty thousand dollars (\$250,000)

In your May 27 letter, you assert that you sent the balance of the required documentation via UPS overnight service. While IDDS did indeed receive that package, the only information included was the database for the WPS-99-020.

In IDDS' May 26 letter, IDDS identified the specific documentation that was not provided. As suggested in your May 27 letter, IDDS has re-reviewed that information and come to the same conclusion: the information was either non-existent, incomplete or wholly inadequate. Indeed, in an effort to ensure that our judgment was not biased, IDDS retained an outside consultant to review the material relating to the Formulation Development Report (item 1 under Schedule B); that consultant's report supports our conclusions described above.



West Pharmaceutical Services, Inc.  
Attention: President  
June 28, 2005  
Page 3

We disagree with your implication that the Side Letter somehow imposes upon IDDS an obligation to be "more specific about additional information to which it believes it's entitled . . ." At this stage, WPS has an obligation to pay IDDS the specified amounts, providing more information to IDDS cannot relieve WPS of that obligation.

The information provided was either not provided, or was provided in a form that was useless and, effectively, amounted to constructive failure to comply with WPS' obligations under the Side Letter.

In light of the above, and the limitation on WPS' obligation to make payments to IDDS set forth in paragraph 3 of the Side Letter, IDDS hereby demands that WPS promptly pay to IDDS one million three hundred ninety-one thousand nine hundred ninety-three dollars (\$1,391,993.00).

If you have any questions regarding the above, please do not hesitate to contact me at your convenience.

Very truly yours,



Jeffrey C. Johnson

cc: West Pharmaceutical Services, Inc.  
101 Gordon Drive  
Lionville, PA 19341  
Attention: General Counsel ✓

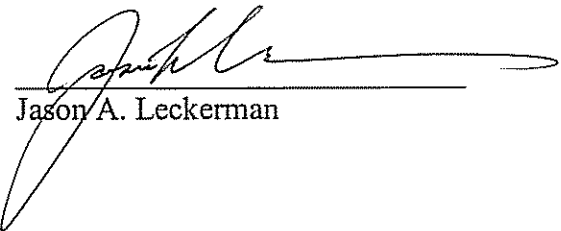
Fred H. Mermelstein, Ph.D. - IDDS  
Mr. Douglas Hamilton - IDDS

**CERTIFICATE OF SERVICE**

I, Jason A. Leckerman, Esquire, hereby certify that, on this day, I caused the foregoing Notice of Removal to be served on the following via first-class U.S. Mail:

Michael L. Kichline  
DECHERT LLP  
4000 Bell Atlantic Tower  
1717 Arch Street  
Philadelphia, PA 19103

Dated: September 12, 2005



Jason A. Leckerman